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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,849	07/15/2005	Birgit C. Schultes	AREX-P01-010	3995

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	**PAPER NUMBER**
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,849	SCHULTES ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *31-34,36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of Group I in the reply filed on 11/23/07 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because as per the previous Office communication, the claimed inventions lack a special technical feature and are therefore restrictable under 35 USC 121 and 372.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 31-34,36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/23/07. Nonstatutory use claims 31/32 are interpreted as drawn to nonelected compositions.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-30,35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,2,9,35 are indefinite in the recitation of "antigen associated with the disease" or "disease associated antigen" because it is unclear what this term means or encompasses. The specification, page 9 indicates that said term means "an antigen with which the disease state is associated" and then give examples of art known tumor related antigen such as PSA. However, it is unclear as to what other antigens are encompassed by said terms in diseases other than cancer. For example, in rheumatoid arthritis, the art recognizes the presence of RF, autoreactive T cells which bind self antigens and increased cytokine levels which mediate certain pathogenic effects of said disease. It is unclear as to whether all three of the aformentioned or any of the aforementioned would be encompassed by the aformentioned definition or whether said definition would encompass one or two of the aformentioned. Regarding

autoreactive T cells it is unclear whether said "disease associated antigen" would encompass an antigen specific for the autoreactive T cell (for example clonotypic TCR)or any antigen found on said T cell.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5,9-19,26,27,29,30,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonnefoy-Berard et al.

Bonnefoy-Berard et al. teach that ATGs (aka xenotypic polyclonal antibodies against thymocytes/lymphocytes) can be used to treat disease in humans such as graft rejection including GVHD and aplastic anemia (see page 4015). Whilst the term "an antigen with which the disease state is associated" is indefinite as per above, for the purposes of the instant rejection the term will be interpreted as encompassing cell surface antigens on effector cells which mediate the aformentioned diseases (aka lymphocytes which mediate graft rejection or GVHD or autoreactive lymphocytes involved in aplastic anemia). Bonnefoy-Berard et al. teach that ATGs contain antibodies which bind the aformentioned lymphocytes (aka specific xenotypic antibody which binds disease associated antigen) and also contains antibodies which do not bind disease associated antigens (xenotypic antibodies which bind non lymphocyte antigens)(see page 4015, first column). Thus, Bonnefoy-Berard et al. disclose treatment with disease antigen specific and nonspecific xenogeneic antibodies as per recited in the claims. The xenogeneic antibodies would inherently have the functional properties recited in the claimed methods because they are xenogeneic antibodies as per recited in the claims. ATG is a clinically used pharmaceutical composition which contains a pharmaceutically acceptable carrier. The ATG is used at a dosage encompassed by that recited in the claims (see page 4105, second column). The nonspecific polyclonal preparation conatins antibodies which are identical to individual monoclonal antibodies. The nonspecific and specific antibodies are from the same animal. Regarding claim 2, the nonspecific and specific antibodies can be in the same composition (see claim 27),

7. Claims 1-17,19,20,28-30,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Noujaim et al. (WO 01/59452).

Noujaim et al. disclose administration of a xenotypic antibody to a patient wherein the antibody can be an antibody not associated with a disease in said patient (see claims 1,4,9 wherein claim 1 encompasses the use of any antibody for predicting efficacy to xenotypic antibody therapy and wherein the antibodies of claim 4 are irrelevant to inflammatory disease or bacterial infection or parasitic infection and viral infection as per claim 9). Noujaim et al. disclose that the patient can then be treated with a xenotypic antibody that is specific for a disease (aka antiviral antibody for viral disease, see page 7, first paragraph). The xenotypic antibodies can be murine antibodies used in humans (see page 9). The various functional parameters recited in the claims are inherent properties of the claimed method because they use the same antibodies. The antibodies contain a pharmaceutically acceptable carrier (see page 6, last paragraph). The antibody can be administered at a concentration of 1 mg/kg (see page 9). Noujaim et al. disclose that the antibody can be murine monoclonal antibody (see page 7).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-22,28-30,35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noujaim et al. (WO 01/59452) in view of Bonnefoy-Berard et al.

Noujaim et al. disclose administration of a xenotypic antibody to a patient wherein the antibody can be an antibody not associated with a disease in said patient (see claims 1,4,9 wherein claim 1 encompasses the use of any antibody for predicting efficacy to xenotypic antibody therapy and wherein the antibodies of claim 4 are irrelevant to inflammatory disease or bacterial infection or parasitic infection and viral infection as per claim 9). Noujaim et al. disclose that the patient can then be treated with a xenotypic antibody that is specific for a disease (aka antiviral antibody for viral

disease, see page 7, first paragraph). The xenotypic antibodies can be murine antibodies used in humans (see page 9). The various functional parameters recited in the claims would occur in the claimed method because they use the same antibodies. The antibodies contain a pharmaceutically acceptable carrier (see page 6, last paragraph). The antibody can be administered at a concentration of 1 mg/kg (see page 9). Noujaim et al. disclose that the antibody can be murine monoclonal antibody (see page 7). Noujaim et al. do not disclose the methods of claims 18,21,22. The therapeutic use of polyclonal xenogeneic antibody (such as ATG) was well in the art (see Bonnefoy-Berard et al.). A routineer would have treated the patients as per claim 21 or 22 depending on the degree of seriousness of the disease. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Noujaim et al. teach the claimed inventions except for the methods of claims 18,21,22 whilst polyclonal xenogeneic antibody (such as ATG) was well in the art and a routineer would have treated the patients as per claim 21 or 22 depending on the degree of seriousness of the disease. One of ordinary skill in the art would have been motivated to do the aforementioned because Noujaim et al. disclose administration of a xenotypic antibody to a patient wherein the antibody can be any antibody not associated with a disease wherein the therapeutic use of polyclonal xenogeneic antibody (such as ATG) was well in the art and a routineer would have treated the patients as per claim 21 or 22 depending on the degree of seriousness of the disease.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1644

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GROUP ~~1600~~ 1600